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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,777	12/29/2000	Hiroyuki Morimoto	02500.000006.	3913

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/647,777	MORIMOTO ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42,43,46,53,63,72,73,80,81,84,91 and 99-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,43,46,53,63,72,73,80,81,84,91 and 99-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/04/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/07/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that the present specification does not provide support for the limitation "a coating film which enhances release in intestine or sustained release, and is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm^{2}". In the Remarks filed 10/24/06, applicant

pointed out page 14, lines 5-9 and experiments 3-4 for support of the limitation "coating film is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm^{2}", however, upon reconsideration, it appears that the experiments do not support the above limitation. Specifically, Experiments 3 and 4 as pointed out by the applicant show that tablet compressed at pressure of 1000 kg/punch (less than 1.3 ton) lost sustained release function and enteric function respectively (see page 66, 4th paragraph through page 68, 1st paragraph).

Claims 42, 43, 46, 53, 63, 72, 73, 80, 81, 84, 91 and 99-102 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a tablet, does not reasonably provide enablement for producing tablet having adequate hardness at tabletting pressure of 0.7-1.3 ton/cm^{2}. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: 1) breadth of the claims; 2) nature of the invention; 3) state of the prior art; 4) amount of direction provided by the inventor; 5) the level of predictability in the art; 6) the existence of working examples; 7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and 8)relative skill in the art. All of the factors have been considered with regard to the claims, with the most relevant factors being discussed below:

Breadth of the claims is broad. Independent claims 42 and 63 require tablet having adequate hardness to withstand the tablet pressure of 0.7-1.3 ton/cm^2.

Amount of direction provided by the inventor, and quantity of experimentation needed to make or use the invention: while the present specification at page 24, second paragraph discloses the present tablet production method can produce a tablet having enough practical level hardness at tabletting pressure of less than or equal to 1 ton/cm^2, the specification fails to describe how to precisely achieve the claimed tabletting pressure greater than 1 ton/cm^2 (up to 1.3 ton/cm^2.

Further, contrary to the claims, the working examples show that the properties of the tablet (e.g., sustained function and enteric function) are destroyed at tabletting pressure of 1000 kg/punch (1 ton) (see pages 66-68). As a matter of facts, experiments 3 and 4 show that the produced tablet that can maintain the functions of a compressed tablet is at a tabletting pressure of 500 kg/punch, which is 0.5 ton. This tabletting pressure is outside of the range recited in the claims, namely, from 0.7-1.3 ton. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to make and/or use the claimed method to prepare tablet with adequate hardness, and maintaining a function of a compressed tablet at tabletting pressure recited in the claims.

As such, the practitioner would turn to trial and error experimentation in order to use the claimed method without guidance from the specification or the prior art.

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

Claim Rejections - 35 USC § 103

Claims 42, 46, 53, 63, 73, 80, 84, 91 and 99-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roche US 5,075,114, in view of Rotman US 4,710,384.

Roche teaches a process for preparing a tablet comprising coating a medicament granule with a sustained release coating, preparing a tablet mixture comprising the coated granule and tablet excpients without steraic acid, and compressing the tablet mixture using standard tabletting procedure to form round chewable tablet (abstract; and column 9, lines 18-68). Roche further teaches the use of lubricant such as stearic acid to lubricate the dye walls and punches during the tablet compression procedure (column 10, lines 4-7).

It is noted that Roche does not teach the claimed tabletting pressure.

Rotman teaches a tablet for oral administration of a sustained release medication is formed by compressing microcapsules of the active principle at a tablet pressure of up to 1.5 tons to form a tablet without substantial breakage of the microcapsules (abstract; and column 2, lines 36-45). Thus, it would have been obvious to one of ordinary skill in the art to compress the tablet of Roche at a tablet pressure that falls within the claimed range without breaking the coating layer on the granules. This because Rotman teaches using conventional tablet pressure of up to 1.5 tons to

compressed chewable tablet without substantial breakage of the coated granules, because Roche teaches the desirability to prepare a chewable tablet by compression without breaking the coating through the compression of the tablet (column 2, lines 62-64), and because Roche teaches the use of conventional tablet compression procedure.

Roche further does not teach the amount of lubricant on the punch and dies. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Accordingly, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select a suitable amount of lubricating agent that would fall within the claimed range. This is because Roche teaches the use of the same lubricating agent for the same purpose, namely, to lubricate the punches and dies walls of the tabletting machine.

Claims 43, 72 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roche US 5,075,114, in view of Rotman US 4,710,384 and Morimoto et al. EP 0 650 826 A1.

Roche is relied upon for the reason stated above. Roche does not teach a tabletting machine with a spraying mean.

Morimoto teaches a tablet compressing method using tabletting machine with lubricant spraying mean (see abstract). The method comprising spraying lubricant

uniformly on the surface of an upper punch, a lower punch, and a die, filling the die with pharmaceutical materials, and compressing the pharmaceutical material to form a drug tablet (columns 2-3 and columns 5-7).

Thus, it would have been obvious to one of ordinary skill in the art to modify the tabletting method of Roche using the tabletting machine with the spraing mean in view of the teaching of Morimoto, because Morimoto teaches the use of a spraying mean to lubricate the die and punch is known in the art, and because Roche teaches the desirability for using lubricant to coat the die and punch walls of the tabletting machine.

Response to Arguments

Applicant's arguments filed 11/07/08 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615